CALDOLOR APPROVED FOR USE IN PEDIATRIC PATIENTS

Caldolor® (ibuprofen) Injection Approved in Pediatric Patients Six Months and Older for Management of Pain and Reduction of Fever

NASHVILLE, Tenn. (Monday, November 23, 2015) – Cumberland Pharmaceuticals Inc. (**NASDAQ:CPIX**), a specialty pharmaceutical company focused on hospital acute care and gastroenterology announced the approval of Caldolor® (ibuprofen) Injection for pediatric patients six months of age and older. The approval was based on data submitted to the U.S. Food and Drug Administration (FDA) as part of a post-marketing commitment following approval of Caldolor in adults in 2009. Caldolor is the first and only injectable non-steroidal anti-inflammatory drug (NSAID) approved for use in pediatric patients.

Caldolor's pediatric approval came after the FDA's review of safety and efficacy data from clinical trials in hospitalized febrile children and in children undergoing tonsillectomy surgery. The pivotal fever study demonstrated a statistically significant greater reduction in temperature for the primary endpoint, an area under the curve analyses of temperature versus time for the first two hours, as well as over the entire dosing interval, as compared to acetaminophen. Seventy-four percent of Caldolor treated patients became afebrile by the end of first dosing interval. A total of 143 pediatric patients, ages six months and older, have received Caldolor in controlled clinical trials. The most common adverse reactions (incidence greater than or equal to 2%) in pediatric patients treated with Caldolor were infusion site pain, vomiting, nausea, anemia and headache.

The recommended dosing for pediatric patients ages six months to twelve years of age is 10 mg/kg up to a maximum single dose of 400 mg Caldolor every four to six hours as necessary. For patients ages twelve to seventeen years of age, the recommended dosing is 400 mg of Caldolor every four to six hours as necessary for management of pain and/or reduction of fever. The product is diluted and administered intravenously over a ten minute infusion and the maximum daily dose in pediatric patients is 2,400 mg.

A.J. Kazimi, CEO – Cumberland Pharmaceuticals said: "FDA's approval of Caldolor for children represents another milestone in Cumberland's mission to provide effective treatment options, particularly for hospitalized patients."